UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA *et al.* *ex rel.* JULIE LONG, Plaintiff, v. JANSSEN BIOTECH, INC., Defendant.	)	Civil Action No. 16-CV-12182-FDS

PLAINTIFF-RELATOR'S MEMORANDUM
IN SUPPORT OF A SINGLE NATIONWIDE TRIAL
FOLLOWING THE COMPLETION OF TARGETED DISCOVERY

Plaintiff-Relator Julie Long respectfully submits that the most efficient, cost-effective, and fair way to resolve her case is through a single nationwide jury trial covering all of Defendant's alleged violations of the False Claims Act ("FCA"), 31 U.S.C §§ 3729(a)(1)(A) & (B), from October 28, 2010 to the present predicated on violations of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b)(2)(B).[1] This approach is consistent with the Court's own stated intentions for phased discovery, avoids duplicative proceedings, and ensures that the jury will have a complete picture of Defendant's alleged unlawful conduct.

From the outset, the Court has emphasized that early discovery limitations were not permanent, but rather a means to "get started" with accounts from Relator's former territory and then, "in all likelihood continue to expand the scope of discovery" once the record developed.[2]

[1] The Court directed the parties to file memoranda presenting their preferences for the scope and structure of trial. *See* Aug. 26, 2025 Conf. Tr. (ECF 482) at 15; Aug. 26, 2025 Electronic Clerk's Notes (ECF 481).

[2] *See* Dec. 14, 2020 Conf. Tr. (ECF 90) at 4.

The Court has repeatedly stressed that the purpose of the initial phase of discovery ("Phase One") was to develop a record for summary judgment,[3] not to fragment Relator's case into multiple trials. This was precisely what Defendant itself requested in its motion for phased discovery, where it urged the Court to limit initial discovery to Relator's territory so that the key issues could be resolved on summary judgment on the basis of a manageable record.[4] After five years of Phase One discovery and several motions to compel and motions for protective orders, once the Court rules on the forthcoming Phase One summary judgment motions, Relator's case will be ripe for a single comprehensive trial upon the completion of targeted supplemental discovery on Defendant's nationwide conduct.

I. INTRODUCTION

A. Relator's Allegations

Relator Julie Long, a former Janssen Area Business Specialist, brings this action under the FCA alleging that Defendant unlawfully pursued a nationwide strategy to induce physicians to prescribe its drugs Remicade and Simponi ARIA, both of which are administered by infusion, by promoting the infusion business model to physicians and providing them free services to support

[3] *See, e.g.*, Apr. 4, 2022 Hr'g Tr. (ECF 304) at 33-34 ("The plan from the beginning was to do discovery on the claims in Central Pennsylvania [and] that would lead to a summary judgment motion. . . ."); Oct. 1, 2021 Conf. Tr. (ECF 186) at 29 ("I am convinced that it makes sense to have phased discovery for the initial phase, I'll call it the relator phase, to be finished and to test that with summary judgment"); Aug. 2, 2021 Hr'g Tr. (ECF 161) at 12 ("[T]he only point of doing phased discovery is so that at the end of that first phase we can say, a-ha, now where are we? . . . What's a sensible means at this point for going forward for assessing the claims and deciding what are we going to pursue and what we aren't going to pursue?").

[4] *See* Def.'s Mem. in Supp. of Mot. for Phased Disc (ECF 87) at 11 ("Phasing discovery according to Defendant's proposal will allow the Court to resolve significant issues on summary judgment ... At the close of the initial phase of discovery, the parties will be able to raise key issues for resolution on summary judgment on the basis of a manageable record. The resulting rulings ... will narrow the issues in dispute for any further phase of the action, for example by allowing the Court to rule that certain support services do not violate the AKS and thus should not be the subject of any further discovery ....").

their infusion businesses.[5] *See, e.g.*, Second Am. Compl. ("SAC") (ECF 55) at ¶¶5, 8, 120, 130, 166. As part of this sales strategy, Defendant had its health care business advisers (called "Area Business Specialists" or "ABSs") regularly meet with physicians and staff of targeted rheumatology and gastroenterology practices, typically high-volume infusers of Remicade and Simponi ARIA, providing free consultative services, programs, and support regarding the operation of their in-office infusion suites ("IOI") to help optimize their efficiency and profitability. *See, e.g.*, *id.* at ¶¶122, 124, 148, 161-66. Defendant also provided free consultative services, programs, and support to targeted physician practices regarding opening or expanding an IOI. *See, e.g.*, *id.* at ¶¶139-44, 160, 166, 188. In addition, Defendant paid outside consultants to supplement the ABSs by providing additional free consultative services, programs, and support to targeted physician practices. *See, e.g.*, *id.* at ¶¶123, 135-37, 140, 149, 163, 166, 176. This collection of consultative services, programs, and practice management support that Defendant provided to physician practices free of charge is referred to herein as "IOI Support."

While Defendant's primary purpose in providing the IOI Support was to influence physicians to prescribe and infuse Remicade and Simponi ARIA to patients, including Medicare beneficiaries, *see, e.g.*, *id.* at ¶¶186-88, these programs and services also provided significant value to the physicians that extended well beyond Defendant's products because they helped physicians open, manage, optimize, and grow their IOIs, where they infused a variety of drugs, not just Remicade and Simponi ARIA. *See, e.g.*, *id.* at ¶¶8, 165-66, 173, 177-85. Relator alleges that the AKS prohibits such remuneration, and that Defendant knew that providing this remuneration to

[5] Infusible drugs like Remicade and Simponi ARIA generate revenue for physician practices. Physicians earn a profit on each vial infused (the difference between the physician's purchase price and the amount charged to patients and insurers, including Medicare, for the drugs) and may also bill for the infusion procedure itself. When physicians prescribe similar drugs that patients self-administer or take at home, they do not profit from the sale or administration of the drugs.

physicians where one purpose was to induce them to prescribe and infuse Remicade and Simponi ARIA to Medicare patients is unlawful, *see, e.g., id.* at ¶¶156, 194-210, but provided it anyway in order to grow and maintain sales of Remicade and Simponi ARIA and sustain the steady flow of enormous profits it made on these infusible drugs. *See, e.g., id.* at ¶¶10, 48-50, 182.

On behalf of the United States, Relator asserts two causes of action under the FCA:

(1) Defendant violated § 3729(a)(1)(A) by knowingly causing physicians to present false bills to Medicare on or after October 28, 2010 to obtain payment for Remicade or Simponi ARIA prescribed and administered to Medicare beneficiaries, as well as the related infusion procedures; and

(2) Defendant violated § 3729(a)(1)(B) by knowingly causing physicians to make false statements regarding compliance with the Anti-Kickback Statute that were material to false bills submitted to Medicare on or after October 28, 2010 to obtain payment for Remicade or Simponi ARIA prescribed and administered to Medicare beneficiaries, as well as the related infusion procedures.

See SAC at Counts I & II.

Both causes of action are predicated on Defendant's willful provision of remuneration—the IOI Support—to physicians from October 28, 2010[6] through 2020 to induce prescriptions and infusions of Remicade and Simponi ARIA to Medicare patients in violation of the AKS, which makes it illegal to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to purchase … [or] order … or recommend purchasing … or ordering

[6] The Court entered judgment on the pleadings as to all claims in the SAC that predate October 28, 2010 pursuant to the parties' stipulation that Relator's claims are governed by the six-year statute of limitations under 31 U.S.C. § 3731(b)(1). *See* Jan. 27, 2023 Order (ECF 372).

[of] any … service or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2)(B).[7]

B. Procedural History

When denying Defendant's motion to dismiss, the Court held that Relator's complaint adequately alleges a nationwide scheme to induce prescriptions of Remicade and Simponi ARIA through unlawful remuneration. *See* Order (ECF 75) at 33. Thereafter, Defendant moved for phased discovery, arguing that initial discovery should be limited to Relator's claims concerning accounts located in the Central Pennsylvania territory as a proportional means of developing "information needed for a realistic assessment of the case." *See* Def.'s Mot. for Phased Disc. (ECF 86) at 2. Defendant contended that "[p]hasing discovery according to [its] proposal [would] allow the Court to resolve significant issues on summary judgment," asserting that "[a]t the close of the initial phase of discovery, the parties will be able to raise key issues for resolution on summary judgment on the basis of a manageable record," and that "[t]he resulting rulings . . . will narrow the issues in dispute for any further phase of the action, for example by allowing the Court to rule that certain support services do not violate the AKS and thus should not be the subject of any further discovery. . . ." *See* Def.'s Mem. in Supp. of Mot. for Phased Disc. (ECF 87) at 11.

The Court granted Defendant's motion, adopting a phased discovery framework under which Phase One discovery was "limited to the practices and programs that relator herself participated in or otherwise witnessed during her time at the company in central Pennsylvania." *See* Sept. 9, 2022 Order (ECF 320) at 2. The Court initially provided instructions concerning the

[7] As the Court recently observed, there are two different theories for establishing FCA liability based on violations of the Anti-Kickback Statute: the "false certification" theory and the "2010 amendment" theory. *United States v. Regeneron Pharm., Inc.*, Civ. No. 20-11217-FDS, 2025 WL 2207299 at *2 (D. Mass. Aug. 4, 2025). Relator is litigating her FCA claims under both theories of liability. *See, e.g.*, SAC at ¶¶26, 28-29, 43, 44, 189-193, Counts I & II.

phased discovery plan and the initial phase at the December 14, 2020 scheduling conference:

> … [D]iscovery will begin first as to the specific allegations of the relator. I'm going to call periodic status conferences to see how all of that is developing, and then we will, in all likelihood, continue to expand that, so to speak, until I think or I'm convinced that we've reached the appropriate level of specificity, meaning I'm not going to order that discovery only as to the relator be completed and nothing else ever until we have resolved all those issues, nor am I going to have us just plunge into . . . hundreds or thousands of different offices or files, so that's going to be the goal, in other words, get started with the claims of the relator, Julie Long, get that discovery well underway, which will inform a whole bunch of issues, at least from my standpoint, about how discovery ought to proceed and what makes sense under the circumstances, and then examine that in another two or three months, and then in all likelihood continue to expand the scope of discovery, so to speak.
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> ***
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> Well, if I have this right, the relator is Julie Long, and she worked in Pennsylvania, and she had a particular area, as I understand it, and she identified specific accounts, I think A through H, if I have that right, and I guess my idea, which is admittedly abstract, is that information be exchanged as to her, that is, discovery taken as to her claims, what she did, what her managers were or told her to do, information she got from people at a national level, if she got any, what happened with these, whatever it is, nine accounts and see where we are at that point.
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> You know, again, in my experience, you tend to learn things. The facts on the ground aren't always what they are as alleged in the complaint. Sometimes they're better for the plaintiff, sometimes they are worse, but they tend to be different, and also there's going to be, I think, a lot of information learned or disclosed about how the company organizes its business, how it trained people, how it supervised people, what writings there were and so on and so forth, and my hope is that once that information is out there, we'll have a better sense of, you know, what the next phase of discovery ought to look like, assuming there is a phase, but it would be focusing on Julie Long's experience, what Julie Long was told, what she read, how she was trained, how she was supervised, what happened with these accounts that she worked with.…

See Dec. 14, 2020 Conf. Tr. (ECF 90) at 4, 10-11. It explained its "intention [was] to defer discovery concerning matters at the nationwide level during that initial phase—except, of course, discovery concerning relevant practices or policies at the national level that were implemented at the local level in central Pennsylvania." *See* Sept. 9, 2022 Order (ECF 320) at 2. The Court made two exceptions to the temporal cutoff for Phase One (the date Relator's tenure at Defendant ended

- February 19, 2016):

> (a) documents created between February 2016 and February 2020 . . . that mention relator Julie Long or her specific allegations or claims; and
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> (b) documents created between February 2016 and February 2020 that concern the termination or phase-out of any of the specific practices or programs that relator Julie Long participated in, or personally observed, while employed by Janssen, or the potential legality or illegality of any such practice or program.

Id. at 3-4.

The Court has repeatedly instructed that at the end of Phase One, it will determine the sufficiency of Relator's allegations and decide whether to broaden discovery to include the full scope of Defendant's nationwide conduct:

- "[P]hasing discovery . . . will provide defendants an opportunity to test the allegations of the complaint by summary judgment, which might narrow or eliminate [Relator's] claims altogether." Sept. 9, 2022 Order (ECF 320) at 2.
- "The plan from the beginning was to do discovery on the claims in Central Pennsylvania [and] that would lead to a summary judgment motion. . . ." Apr. 4, 2022 Hr'g Tr. (ECF 304) at 33-34.
- "I am convinced that it makes sense to have phased discovery for the initial phase, I'll call it the relator phase, to be finished and to test that with summary judgment. . . ." Oct. 1, 2021 Conf. Tr. (ECF 186) at 29.
- "[T]he only point of doing phased discovery is so that at the end of that first phase we can say, a-ha, now where are we? . . . What's a sensible means at this point for going forward for assessing the claims and deciding what are we going to pursue and what we aren't going to pursue?" Aug. 2, 2021 Hr'g Tr. (ECF 161) at 12.

C. Present Posture

Phase One fact discovery is now complete, expert discovery is underway[8], and summary

[8] With regard to use of expert testimony during the Phase One summary judgment process, the Court required full Rule 26(a)(2) disclosures with Relator making her disclosures first, then Defendant, followed by Relator disclosing rebuttal expert opinions. *See* May 14, 2024 Order (ECF 444); Apr. 3, 2025 Order (ECF 473); Aug. 19, 2025 Order (ECF 480). In adopting this schedule, the Court rejected Relator's position that expert discovery should be limited to opinions Defendant

judgment motions are due in April 2026. In accordance with the Court's directives and limitations regarding Phase One, the discovery Relator has obtained to date has focused on the IOI Support that Defendant provided during the period Relator worked as an ABS (2003 to February 2016) to the sample group of accounts from within her former territory. The evidence shows, among other things, that Defendant provided the IOI Support to targeted physician practices in Central Pennsylvania including the sample group of accounts, and that the IOI Support provided in Central Pennsylvania was part of a national marketing strategy under which the IOI Support was also provided to targeted physicians practices scattered across the country. The evidence also shows that Defendant continued providing the IOI Support in Central Pennsylvania and elsewhere after Relator left the company in February 2016 through at least 2020.

A jury trial is currently set for three weeks beginning October 26, 2026. *See* Aug. 26, 2025 Electronic Clerk's Notes (ECF 481); Aug. 26, 2025 Conf. Tr. at 16. At the August 26, 2025 status conference, the Court directed the parties to file memoranda setting forth their respective positions on the proper scope and structure of trial. *See* Aug. 26, 2025, Conf. Tr. at 14-15. As demonstrated below, once Phase One summary judgment is resolved, the case will be ready for targeted supplemental discovery on Defendant's nationwide conduct, after which a single comprehensive trial should be held to resolve all claims efficiently and fairly.

II. A SINGLE NATIONWIDE TRIAL IS THE MOST EFFICIENT, COST-EFFECTIVE, AND FAIR WAY TO RESOLVE THIS CASE

As the Court directed, Relator has considered how to structure and best streamline the resolution of this matter. The most efficient, cost-effective, and fair path is a single nationwide

might use in support of its Phase One summary judgment motion and any responsive expert opinions Relator would offer in opposition. *See* Pl.'s Resp. Objecting in Part to Def.'s Req. for Status Conf. (ECF 411) at 4-5. Phase One expert discovery is set to be completed by January 30, 2026. *See* Aug. 19, 2025 Order (ECF 480).

jury trial covering all alleged false claims from October 28, 2010 to the present. Splitting Relator's causes of action into two partial trials—one confined to Phase One accounts and the second (likely occurring years later) addressing nationwide claims—would delay final resolution of this action, impose unnecessary burdens on the Court and the jurors, and dramatically increase the cost to adjudicate Relator's claims.

This Court has consistently emphasized that Phase One was a provisional step to test Relator's allegations, and it will conclude once the Court rules on the summary judgment motions that will be filed this April. If final summary judgment is not entered in favor of Defendant, a reasonable period for a second phase of targeted discovery and any necessary supplementation of expert disclosures should follow in order to address Defendant's nationwide conduct for the full period that the alleged illegal remuneration was provided (lifting the February 2016 temporal end date that was used for Phase One). Because Phase One has already revealed that the IOI Support program was driven by national systems and policies, and because Defendant now has a clear understanding of the Court's discovery expectations given the extensive litigation over discovery during Phase One, this supplemental discovery can be completed quickly and efficiently.

By contrast, conducting two partial trials would only prolong and complicate this litigation. A first trial limited to the Phase One sample group of accounts during the truncated time period of October 28, 2010 to February 19, 2016 would inevitably be followed by a second nationwide trial to address the balance of Relator's claims covering the full damages period (October 28, 2010 to the present), plus a rehashing of the claims concerning the Phase One sample accounts for the time period of February 20, 2016 to the present day, which has been excluded during Phase One. This two-trial approach would delay final resolution of Relator's action for years, likely pushing a nationwide trial into 2028 or later, and would require the Court, the parties, and jurors to revisit

overlapping issues. It also risks two rounds of post-trial appeals before all claims can be adjudicated. As Defendant has indicated that a Phase One trial would likely not result in a meaningful settlement of all claims, a single nationwide trial is the only way to avoid duplicative litigation, conserve resources, and ensure the jury hears the full case (and hears it only once). The Court should, therefore, set this matter for a single nationwide trial, ensuring a complete and final resolution of all Relator's claims through a single proceeding.

III. CONCLUSION

Relator Julie Long respectfully submits that the most efficient, cost-effective, and fair way to resolve this action is through a single nationwide jury trial covering all of Defendant's alleged violations of the False Claims Act, 31 U.S.C §§ 3729(a)(1)(A) & (B), from October 28, 2010 to the present predicated on violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(B). Having only one nationwide trial will allow a single jury to hear and consider the full scope of the evidence, avoid duplicative proceedings, conserve judicial resources, and provide a complete and final adjudication of the entirety of Relator's claims much more quickly than could be achieved if multiple trials are required.

Dated: September 26, 2025

Respectfully submitted,

/s/ Casey M. Preston

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CERTIFICATE OF SERVICE

I hereby certify on this 26th day of September, 2025, that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/ Casey M. Preston
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